Remarks

Claims 1-10, 14, 16-20 and 24-34 are pending. Claims 14, 17, 18 and 32 are allowed. Claims 1-9, 19, 20, 24-31 and 34 are rejected. Claims 10 and 16 are objected to.

Interview

Applicants thank the Examiners for the very helpful in-person interview conducted on February 17, 2004.

Extension of Time

Filled herewith is a claim for extension of time for one month for filing this response.

Claim Rejections under 35 U.S.C. §112

Claim 34 has been rejected under 35 U.S.C. §112 first paragraph because, according to the Examiner, it fails to describe in the specification a chin strut that extends non-vertically from the chin to the plate. Applicants appreciate the discussion allowed on this element during the February 17, 2004 interview. It was agreed that describing the strut as non-vertical was ambiguous so Applicants have modified the claim to eliminate the ambiguity without narrowing the claim or adding new matter. As was noted during the interview, FIG. 6A shows a chin strut extending "non-vertically" between the chin support of the cervical collar and the sternum area of the chest plate. Claim 34 has been amended to describe the direction in which the chin strut extends by designating the starting and ending points, i.e. "chin support" and "chest plate sternum area." Paragraph 23 also describes the chin strut position. The amendment to Fig. 1A and paragraph 23 further identifies an end point of the chin strut by labelling the chin support 112 and describing the attachment of the strut to the chin support, as had been claimed.

Claim Rejections under 35 U.S.C. §102

Claims 1-5, 7-9, 19-20, 24, 28-29 and 33 are rejected under 35 U.S.C. §102(e) as being anticipated by Garth. With the exception of claim 24, the aforementioned claims have either been cancelled or amended to depend on new claim 35. New claim 35 is not anticipated by Garth.

Claim 35 includes an anterior assembly having a <u>lower plate adjustably attached to an upper plate (p.5, paragraph 22)</u>. Claim 35 also includes a chin strut having an attachment point

for <u>detachable attachment</u> of the chin strut to a chin support of a cervical collar (p.6, paragraph 23). Garth does not disclose either of these claimed elements.

Very significantly, Garth does not disclose a support attached to a "chin" support. Garth's front strut attaches to points below any chin support (see FIG. 3, attachment 109 for support 120). Having the chin strut attached to a chin support is important because it prohibits or reduces flexing forward of the neck. This was shown during the February 17, 2004 interview by providing a product embodying Applicants' claimed invention and a product embodying Garth's disclosures. The demonstration showed that Garth's strut attachment toward the base of the neck allowed the head to move up and down, but Applicants' attachment at the chin support inhibited such movement.

Garth clearly does not disclose a lower plate adjustably attached to an upper plate. Garth's chin strut is not detachable from the collar. Garth discloses a strut attached to a collar with pivotal or hinged attachments 109 & 109A (col. 3, lines 58-67). The pivotal attachments permit the strut mechanism to be rotated in relation to the neck collar (col. 3, line 66 - col. 4, line 1; and col. 4, lines 26-34) for the purpose of access to the chest without removing the device entirely. These are the limitations disclosed in Garth with respect to the strut attachment to the collar. Garth does not disclose that the collar is detachable from the strut. Garth designates when his disclosed fasteners are detachable. For example, Garth discloses detachable fasteners to hold various portions of the collar to one another, not parts of the collar to the strut (col. 3, lines 27-45). Applicants respectfully submit that the Examiner is reading more into Garth's disclosure than exists.

As Garth does not disclose these elements that are contained in Applicants' independent claim 35, it, and claims 36-43, which depend thereon, are not anticipated by Garth.

Claim 24 was also rejected as being anticipated by Garth. Claim 24 includes a back plate that is free to move with respect to the cervical collar. This concept was described during the February 17, 2004 interview and it was shown that when the cervical collar is not rigidly connected to the back plate the desired alignment of the spine is better maintained. This is a novel concept and is neither taught nor suggested by Garth. The Examiner states that Garth's back plate is "capable" of being free from attachment to the cervical collar, however, Garth does not disclose such an embodiment. To the contrary, Garth teaches only attaching a back plate to a

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collar (Fig. 2 and col. 5, lines 23-24). Nowhere is it indicated that Garth recognizes that it may be beneficial for the back plate that is free to move with respect to the cervical collar. Applicants' invention of claim 24 acts to reduce compensatory motion, unlike Garth's over-constrained system. In an over-constrained system, as disclosed in Garth, unwanted motion is created to compensate for the inability to move in a manner to accommodate certain activities, such as transitioning from a sitting position to a standing position, or a prone position to a sitting position. There is less constraint on the system when the back is free to move from the collar allowing better stabilization of the cervical junctions. Garth's invention functions to maintain relative position of the brace components. Therefore, as a patient moves from supine to standing or sitting, undesirable or compensatory forces may be imposed upon the neck and back causing it to move in an undesirable fashion. A patient using applicants' claimed invention may lay flat on his/her back with the head in the same relative position as when upright, which is the normal tendency. Garth's invention would require a patient to have a different relative position of the neck and back, whether prone, standing or sitting. As this is not natural, it can be very uncomfortable. Accordingly, as Garth does not disclose applicants' "free-moving back", claim 24 is patentable over Garth.

New claim 25 is a method claim based on the apparatus claim 24 and can be performed utilizing the apparatus of claim 24. Accordingly, for the same reasons as claim 24 is patentable over Garth, so is claim 51.

Withdrawal of the 35 U.S.C. §102 rejections are therefore, respectfully requested.

It is noted that Applicants have replaced the term "chest plate" with "anterior plate assembly" in the claims because the specification more clearly describes the term. It is also more in keeping with the language of the majority of the specification. The anterior plate assembly, preferably comprises two plates (p.5, paragraph 22), but the invention is not limited to such and encompasses one or more plates.

Claim Rejections under 35 U.S.C. §103

Claim 6 is rejected under 35 U.S.C. §103(a) as being unpatentable over Garth. This rejection is respectfully traversed. Unrelated to this rejection, claim 6 has been cancelled.

Claims 25-27, 30 and 31 are rejected under 35 U.S.C. §103(a) as being unpatentable over Garth in view of Mattingly. This rejection is respectfully traversed. Unrelated to this rejection, claims 25, 27 and 30 have been cancelled. Claim 31 is dependent on claim 35, and therefore, for reasons stated above, is patentable over Garth. Claim 26 has been amended to depend on new claim 49. New claim 49 is a method claim that parallels allowed claim 32. The method described in claim 49 can be performed with the apparatus of claim 32 and also is not anticipated by Garth. Garth does not disclose attaching a chin strut from the cervical collar to an anterior assembly, and adjusting a rear strut and locking it, with an eccentric lever, to a back plate. Therefore, neither claim 49, nor claims 26 and 50, which depend thereon, are anticipated by Garth.

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Mattingly does not overcome the shortcomings of Garth. First, Mattingly is not analogous art because Mattingly does not disclose a cervical collar or a device to be used with a cervical collar as is claimed by Applicants. Mattingly is a halo brace. Furthermore, there is no motivation to combine the teachings of Mattingly with that of Garth. Additionally, Garth in view of Mattingly does not disclose claimed elements such as the detachable chin strut. Accordingly, withdrawal of the 35 U.S.C. §103 rejections are respectfully requested.

Allowable Subject Matter

Applicants thank the Examiner for allowance of claims 10 and 16 when rewritten in independent form. Accordingly, claims 44 and 48 have been added.

New claim 44 encompasses limitations of claim 10 and includes all limitations of the base claim and any intervening claims (namely, claims 1, 7 and 9). It is noted that one element in this combination was added as dependent claim 46. The element is the straps for securing the back to the anterior plate assembly. Based on the Examiner's reasons for allowance it was determined that this element could be a dependent claim.

New claim 48 encompasses limitations of claim 16 and includes all limitations of the base claim and any intervening claims (namely, claims 1 and 28).

Prior Art

Applicants note the prior art made of record and not relied upon.



Conclusion

Applicants believe that all pending claims are allowable over the cited prior art and respectfully request early and favourable notification to that effect. Applicants welcome any further discussion regarding the claims to move the case toward allowance.

Respectfully submitted, SCHNADER HARRISON SEGAL & LEWIS LLP

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